

REMARKS

I. Status of the Application

Claims 18-37 and 54-63 are currently presented to the Examiner. Claims 25 and 33 are amended with this response. Support for the amendments can be found at least on pages 5, 6, and 8 of the Pending Application, as well as Example 1 of U.S. Provisional Appl. No. 60/004,258, which was incorporated by reference and added to the present invention in Example 6. New claims 64-81 are also added with this response. Support for these new claims can be found at least on pages 7, 9, 11, 12, and 14.

The Examiner has rejected claim 25 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner has also rejected claims 18-37 and 54-63 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,098,303 (hereinafter "Fischer") in view of U.S. Patent No. 5,089,254 (hereinafter "Coulson") or U.S. Patent No. 4,666,708 (hereinafter "Goldemberg"). As explained below, Applicant respectfully traverses these rejections and requests withdrawal of the same.

Applicant further requests that the Examiner withdraw his objection to the abstract of disclosure because, as outlined below, the abstract is now one paragraph in length.

II. Rejection under 35 U.S.C. § 112

Claim 25 stands rejected under 35 U.S.C. § 112 as indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. However, Applicant respectfully submits that this rejection is remedied by the current amendment to the claim.

III. Rejection under 35 U.S.C. § 103

As set forth above, claims 18-37 and 54-63 were rejected under 35 U.S.C. § 103(a) as obvious over Fischer, in view of Coulson or Goldemberg. However, it is respectfully submitted that the Examiner has failed to make a prima facie case of obviousness with regard to claims 18-37 and 54-63 because none of the cited references, alone or in combination, disclose or suggest the invention claimed in the Pending Application.

The Pending Application discloses a method for whitening the teeth of a subject. The method has two main steps that must be done sequentially. The first step involves ensuring that the pH of the tooth surface is between about 7 and about 10. Once the pH of the tooth surface is

between about 7 and about 10, the second step of the method is implemented. The second step involves contacting the teeth with a tooth bleaching composition that contains a hydrogen peroxide-containing compound.

The order of the above steps is critical as “[a]n important aspect of the present invention is the finding that the efficiency of the bleaching reaction in a tooth using a chemical tooth-bleaching agent such as hydrogen peroxide can be significantly enhanced at a pH greater than 5.5....” (See the Pending Application, page 5, lines 20-24). Consequently, the enhanced efficiency of the bleaching reaction allows for the “use of reduced concentrations of hydrogen peroxide in tooth-bleaching compositions in order to achieve effective tooth bleaching in a contact time of less than one hour.” (See the Pending Application, page 5, lines 7-10).

In contrast, Fischer discloses a method of bleaching a patient’s teeth which utilizes high viscosity, sustained release dental compositions that are in contact with a patient’s teeth for more than one hour. Specifically, Fischer teaches that “[a]n important characteristic of the high viscosity, sustained release dental compositions within the scope of the present invention is that the compositions are still observed, from a clinical standpoint, after about 3 to 7 hours of normal daytime activity and after about 7 to 10 hours of sleep.” (Fischer, column 7, lines 27-32). Further, Fischer suggests that “recommended treatment times start at approximately 18-20 hours a day.” (Fischer, column 9, lines 9-11). Thus, Fischer does not disclose “effective tooth bleaching in a contact time of less than one hour.” (See the Pending Application, page 5, lines 7-10).

Fischer also does not teach or suggest achieving a pH at the tooth surface between about 7 to about 10 before whitening a patient’s teeth. In fact, the Examiner correctly points out that Fischer is “silent regarding an alkaline pre-treatment step.” (July 28, 2004 Office Action, page 4). Therefore, the fact that Fischer suggests that a patient’s teeth should be cleaned before whitening is irrelevant. Especially because Fischer does not teach or suggest a method of cleaning a patient’s teeth. It follows then that Fischer does not teach or suggest the method outlined by the Pending Application. As such, claims 18, 23, 29, 32, 35, and 54 are allowable over Fischer.

Claims 18, 23, 29, 32, 35, and 54 are allowable over Fischer even if it is combined with Coulson. Coulson does not teach any aspect of the method claimed in the Pending Application. Rather, Coulson teaches an anti-caries oral composition which addresses the problem of the loss

of availability of the fluoride active component due to reaction with other ingredients of the dentifrice during the time period of manufacture to use by the consumer. (Coulson, column 1, lines 19-21).

Particularly, Coulson suggests that the loss of availability of the fluoride active component is reduced in a composition comprising a fluorine-containing anti-caries agent and a particulate hydroxyapatite abrasive material. (Coulson, column 1, lines 29-37). In addition, Coulson teaches that the loss of availability of the fluoride active component can be further reduced “by treating the surface of the particulate hydroxyapatite with compounds that block the hydroxy groups present at the surface of the particulate hydroxyapatite, prior to its coming in contact with the fluorine-containing anti-caries agent. This can be achieved by treating e.g. *washing the hydroxyapatite* [the abrasive material] with a suitable hydroxy-blocking agent *prior to its incorporation into the dentifrice*.” (Coulson, column 1, lines 39-52) (emphasis added).

In light of the above, Applicant respectfully submits that the Examiner has mischaracterized the specification of Coulson. Coulson does not teach “pre-treating the teeth with an agent which blocks hydroxy groups.” (July 28, 2004 Office Action, page 4). Rather, Coulson teaches treating the hydroxyapatite with a hydroxy-blocking agent. Moreover, Coulson does not disclose the pH of the tooth surface. Rather, Coulson discloses the total fluoride in supernatant from “surface-treated Captal [a trade name for hydroxyapatite] at pH 8.” (Coulson, column 4, lines 1-22). Accordingly, Fischer combined with Coulson does not teach or suggest the method outlined by the Pending Application. Thus, claims 18, 23, 29, 32, 35, and 54 are allowable even if Fischer is combined with Coulson.

Likewise, claims 18, 23, 29, 32, 35, and 54 are allowable over Fischer in view of Goldemberg. Goldemberg disclose a alkaline dental rinse formulation, that upon contact to the teeth, loosens plaque and allows it to be more easily brushed away. (Goldemberg, column 1, lines 9-14 and column 3, lines 1-4). In particular, Goldemberg identifies sodium benzoate, which is not an alkalizing agent, as the active reagent in the dental rinse formulation that loosens plaque. (Goldemberg, column 5, lines 32-51).

Goldemberg does not suggest that the “bleaching reaction in a tooth using a chemical tooth-bleaching agent such as hydrogen peroxide can be significantly enhanced at a pH greater than 5.5 [at the tooth’s surface].” (See the Pending Application, page 5, lines 20-24). Goldemberg is also silent with regards to the pH of the tooth’s surface. Moreover, Goldemberg

does not even mention tooth whitening. In fact, Goldemberg describes the subsequent use of a conventional dentifrice, rather than any specific specialized composition comprising “a chemical tooth-bleaching agent such as hydrogen peroxide...” (See Goldemberg Column 8, lines 60-63; see the Pending Application, page 5, lines 21-22). One of skill in the art would know that conventional dentifrices do not contain hydrogen peroxide or hydrogen peroxide precursors. Only specialized dentifrices, such as dentifrices used for teeth whitening, may contain such peroxide compounds. Hence, Fischer combined with Goldemberg does not teach or suggest the method, outlined by the Pending Application. Claims 18, 23, 29, 32, 35, and 54 are therefore allowable even if Fischer is combined with Goldemberg.

There is, however, no suggestion to combine the above references. In addition, even if one skilled in the art combined the cited references, such a combination would not achieve the method disclosed in the Pending Application. Consequently, because a combination of the cited references does not render obvious the claimed method of the Pending Application, claims 18, 23, 29, 32, 35, and 54 are allowable. Claims 19-22 are also not obvious and are allowable as they depend on claim 18; claims 24-28 are also not obvious and are allowable as they depend on claim 23; claims 30 and 31 are also not obvious and are allowable as they depend on claim 29; claims 33 and 34 are also not obvious and are allowable as they depend on claim 32; claims 36 and 37 are also not obvious and are allowable as they depend on claim 35; and claims 55-63 are also not obvious and are allowable as they depend on claims 23, 32, 35, and 54.

IV. Abstract of Disclosure

The Examiner has objected to the Applicant’s abstract of disclosure because the abstract is not one paragraph in length due to an amendment dated 2/10/03, which added a second paragraph. In order to comply with the requirements outlined in MPEP § 608.01(b), the Applicant respectfully requests that the abstract text introduced with the 2/10/03 amendment be added to end of the originally submitted abstract. Thus, the abstract should now read as follows:

The present invention relates to improved dental compositions and methods for bleaching teeth. More specifically, this invention is directed towards hydrogen peroxide-containing compounds that are maintained at a substantially constant pH range of 6.0-10.0 during the tooth-bleaching procedure in the presence of a calcium chelating agent. *Another embodiment of the present invention is directed towards methods of whitening teeth by applying to the teeth a composition having a pH of between about 7 and about 10 and then contacting the teeth with a hydrogen peroxide-containing compound in an amount effective to whiten teeth.*

(The text introduced with the 2/10/03 amendment is emphasized.) In light of this change, Applicant submits that he has overcome the Examiner's objection and therefore it should be withdrawn.

V. Conclusion


With entry of the above amendment and in view of the foregoing remarks, it is respectfully submitted that claims 18-37 and 54-81 are in condition for allowance.

None of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

It is respectfully submitted, in view of the foregoing Amendment and Remarks, that all of the objections and rejections in the Office Action dated July 28, 2004 have been overcome and should be withdrawn. Applicant respectfully requests early and favorable notification to that effect. The Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,

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